[*We redact certain identifying information and certain potentially privileged, confidential, or proprietary information associated with the individual or entity, unless otherwise approved by the requestor.*]

Issued: December 28, 2007

Posted: January 14, 2008

[Name and Address Redacted]

Re: OIG Advisory Opinion No. 07-22

Ladies & Gentlemen:

We are writing in response to your request for an advisory opinion concerning an arrangement in which a hospital has agreed to share with a group of anesthesiologists a percentage of the hospital's cost savings arising from the anesthesiologists' implementation of a number of cost reduction measures related to anesthesia services provided during cardiac surgical procedures (the "Arrangement"). The cost savings are measured based on the anesthesiologists' reduction of waste and use of specific devices and supplies during designated cardiac surgery procedures. You have inquired whether the Arrangement constitutes grounds for sanctions arising under: (i) the civil monetary penalty for a hospital's payment to an anesthesiologist to induce reductions or limitations of services to Medicare or Medicaid beneficiaries under the anesthesiologist's direct care, sections 1128A(b)(1)-(2) of the Social Security Act (the "Act"); or (ii) the exclusion authority at section 1128(b)(7) of the Act or the civil monetary penalty provision at section 1128A(a)(7) of the Act, as those sections relate to the commission of acts described in section 1128B(b) of the Act, the anti-kickback statute.

You have certified that all of the information provided in your request, including all supplementary letters, is true and correct and constitutes a complete description of the relevant facts and agreements among the parties.

In issuing this opinion, we have relied solely on the facts and information presented to us. We have not undertaken an independent investigation of such information. This opinion is limited to the facts presented. If material facts have not been disclosed or have been misrepresented, this opinion is without force and effect.

Based on the information provided and the totality of the facts as described and certified in your request for an advisory opinion and supplemental submissions, we conclude that: (i) the Arrangement could constitute an improper payment to induce reduction or limitation of services pursuant to sections 1128A(b)(1)-(2) of the Act, but that the Office of Inspector General ("OIG") would not impose sanctions on the requestors of this advisory opinion, [names redacted] (collectively, the "Requestors"), in connection with the Arrangement; and (ii) the Arrangement could potentially generate prohibited remuneration under the anti-kickback statute, if the requisite intent to induce or reward referrals of Federal health care program business were present, but that the OIG would not impose administrative sanctions on the Requestors under sections 1128(b)(7) or 1128A(a)(7) of the Act (as those sections relate to the commission of acts described in section 1128B(b) of the Act) in connection with the Arrangement.

This opinion may not be relied on by any persons other than the Requestors and is further qualified as set out in Part IV below and in 42 C.F.R. Part 1008.

I. FACTUAL BACKGROUND

A. Parties

The Hospital. [Name redacted] (the "Hospital") is an acute care hospital in [city and state redacted], that offers a broad range of inpatient and outpatient hospital services, including cardiac surgery services. The Hospital is a participating provider in the Medicare and Medicaid programs.

The Anesthesiology Group. [Name redacted] (the "Anesthesiology Group") is a professional corporation comprised only of anesthesiologists who are licensed in [state redacted], have active medical staff privileges at the Hospital, and whose practice includes the provision of cardiac anesthesia services. The Anesthesiology Group is the only group administering cardiac anesthesia at the Hospital. The Anesthesiology Group's practice is limited to the administration of anesthesia ancillary to procedures performed by other physicians. It does not furnish pain management or similar free-standing professional services or order or furnish any separately billable Hospital services. The Anesthesia Group bills and collects its own professional fees; it does not reassign such fees to the Hospital.

The Program Administrator. The Hospital engaged [name redacted] (the "Program Administrator") to administer the Arrangement. The Program Administrator collected data

and analyzed and managed the Arrangement.[1] The Hospital paid the Program Administrator a monthly fixed fee certified by the Requestors to be fair market value in an arm's-length transaction for services provided by the Program Administrator under the Arrangement. The fee was not tied in any way to cost savings or the Anesthesiology Group's compensation under the Arrangement.

B. The Arrangement

Under the Arrangement, the Hospital agreed to pay the Anesthesiology Group a share of cost savings directly attributable to specific changes in the Anesthesiology Group's anesthesia practices. The Requestors implemented the Arrangement – and the Anesthesiology Group began performance of the specific changes in operating room practices – prior to requesting this advisory opinion. However, the Hospital has not paid amounts owed to the Anesthesiology Group under the Arrangement pending the outcome of this opinion.[2] Thus, we are treating the Arrangement as an existing arrangement for purposes of this advisory opinion. The Requestors have certified that the Hospital will make payments owed under the Arrangement upon receipt of a favorable advisory opinion.

The Program Administrator conducted a study of the historic anesthesia practices at the Hospital's cardiac surgery department and identified five specific cost-savings opportunities. The results of the Program Administrator's study of the Anesthesiology Group and the specific cost-savings opportunities are summarized in a document entitled "Executive Summary of Value Share for Cardiac Anesthesia" (the "Executive Summary").[3] The Hospital and the Anesthesiology Group reviewed the recommendations and conclusions outlined in the Executive Summary for medical appropriateness, and each adopted them.

In general, the Executive Summary recommended that the Anesthesiology Group change its operating room practices to curb the inappropriate use or waste of medical supplies. The

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[1]The Program Administrator has developed software products that measure cost, quality, and utilization on a national basis. The products are certified by both the American College of Cardiology and the Society of Thoracic Surgery.

[2]Nonpayment of amounts owed pursuant to a contractual agreement does not, by itself, absolve parties from liability under the fraud and abuse laws.

[3]The Executive Summary for the Anesthesiology Group is attached to this advisory opinion as Appendix A. This opinion is based on the specific cost savings recommendations and associated facts set forth in the Executive Summary. Similar cost savings recommendations involving different facts could produce a different result.

Executive Summary identified five specific recommendations that can be roughly grouped into the following three categories.

- "*Use as Needed" Items*. The Anesthesiology Group was to eliminate the routine use in the specific cardiac procedures covered by the Arrangement of (i) a specific drug and (ii) a device used to monitor patients' brain function (when the reduction occured in conjunction with compensating changes in clinical practice) (hereafter, the "use as needed" recommendations).[4] The Requestors have certified that the individual anesthesiologists made patient-by-patient determinations as to whether the items were clinically indicated in particular procedures and that the items remained readily available to the anesthesiologists. The Requestors further certified that any change in the use of these items did not adversely affect patient care.[5]

- *Product Substitution*. The Anesthesiology Group was to substitute, in whole or in part, less costly items for items currently being used by the anesthesiologists during the covered cardiac procedures (hereafter, the "product substitution" recommendations). Specifically, one recommendation involved the use of a specific catheter, and the other involved a nasogastric tube made with a less expensive material.

- *Product Standardization*. The Anesthesiology Group was to standardize the use of certain fluid warming hot lines where medically appropriate. For this category, the Anesthesiology Group was required to work with the Hospital to evaluate and clinically review vendors and products.[6] The Anesthesiology Group agreed to use the selected product where medically appropriate, which might have required additional training or changes in clinical practice.

The Arrangement contained several safeguards intended to protect against inappropriate reductions in services. The Executive Summary clearly identified with specificity each "use as needed" and product substitution recommendation. For the catheter substitution recommendation, the Arrangement used objective historical and clinical measures

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[4]The Executive Summary identified with specificity the products at issue.

[5]In the case of the device, the Requestors indicate its use in the covered procedures is not supported by medical literature and that the American Society of Anesthesiology has issued a practice advisory stating that its routine use is not indicated. With respect to the drug, the Requestors indicate that its routine use is not supported by evidence and that its use significantly increases costs without proven increases in benefits.

[6]The Executive Summary identified with specificity the type of product at issue.

reasonably related to the practices and the patient population at the Hospital, and, in some cases, data at comparable hospitals to establish thresholds beyond which no savings accrued to the Anesthesiology Group. The Executive Summary indicated that a less expensive catheter could appropriately be used in 90% of cases; accordingly, the savings achievable by using less expensive catheters was limited to 90% of cases. The Anesthesiology Group will receive no share of cost savings attributable to using less expensive catheters in more than 90% of cases.[7]

Further, the Program Administrator tracked and measured the Hospital's performance of the covered cardiac procedures against the quality indicators established by the Society of Thoracic Surgeons ("STS") throughout the base year and contract year (as defined below). According to the Requestors, the STS quality indicators against which all of the Arrangement's recommendations were evaluated reflect objective hospital baselines and incorporate specificity sufficient to correlate outcomes with operating room practices. The indicators are action-specific and not simply based on isolated patient outcome data unrelated to specific changes in operating room practices. No cost sharing amounts were allocated to the Anesthesiology Group for procedures involving reductions in historical STS quality indicators.

Importantly, with respect to the recommendation to standardize fluid warming hot lines, the Requestors have certified that the individual anesthesiologists made patient-by-patient determinations of the most appropriate fluid warming hot lines, and the availability of the full range of lines was not compromised by the product standardization. The Requestors have further certified that individual anesthesiologists still had available the same selection of lines after implementation of the Arrangement as before and that the economies gained through the Arrangement resulted from inherent clinical and fiscal value and not from restricting the availability of warming hot lines.

Finally, the Requestors have certified that all items covered by the Arrangement remained readily available for use by the anesthesiologists after implementation of the Arrangement.

According to the Program Administrator, to the extent implemented in accordance with the Executive Summary's specifications, the five recommendations presented substantial cost

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[7]The Arrangement did not include comparable objective utilization thresholds for recommendations to eliminate use of the brain function monitor and to use a nasogastric tube made of a less expensive material in the covered cardiac procedures. The Requestors have certified that the former recommendation was consistent with a practice advisory issued by the American Society of Anesthesiology and that the latter recommendation was consistent with the routine standard of care for the covered procedures.

savings opportunities for the Hospital without any adverse impact on the quality of patient care.

The Hospital intends to pay the Anesthesiology Group 50% of the cost savings achieved by implementing the five recommendations in the Executive Summary for a period of one year. At the end of the applicable year (the "contract year"), cost savings were calculated separately for each of the five recommendations; this precluded shifting of cost savings and ensured that savings generated by utilization reduced below the set targets, as applicable, were not credited to the Anesthesiology Group. The payment, when made, will constitute the entire compensation paid to the Anesthesiology Group for services performed pursuant to the contract memorializing the Arrangement between the Anesthesiology Group and the Hospital. For purposes of calculating the payment to the Anesthesiology Group, the cost savings were calculated by subtracting the actual costs incurred during the contract year for the items specified in the five recommendations when used by anesthesiologists in the Anesthesiology Group during the specified surgical procedures (the "contract year costs"[8]) from the historic costs for the same items when used during comparable surgical procedures in the base year (the "base year costs"[9]). The current year costs were adjusted to account for any inappropriate reductions in use of items beyond the targets set in the Executive Summary or in connection with reductions in the STS quality indicators. The payment to the Anesthesiology Group was calculated to be 50% of the difference between the adjusted contract year costs and base year costs.

The Hospital is obligated to make an aggregate payment to the Anesthesiology Group, which distributes its profits to each of its members on a per capita basis. Calculation of the payments to the Anesthesiology Group was also subject to the following limitations:

- If the Anesthesiology Group's volume of procedures payable by a Federal health care program in the contract year exceeded the volume of like procedures payable by a Federal health care program performed in the base year, there was no sharing of cost savings for the additional procedures.

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[8]The current year was the twelve-month period for which the Anesthesiology Group is to be compensated under the Arrangement.

[9]The "base year" will be the twelve months preceding the current year of the arrangement. For purposes of this opinion, the Arrangement is limited to a one-year term; accordingly, this opinion is without force and effect with respect to any future renewal or extension of the Arrangement. Notwithstanding, we note that any renewal or extension of the Arrangement should incorporate updated base year costs.

- To minimize the potential for steering of more costly patients to other hospitals, the case severity, ages, and payors of the patient population treated under the Arrangement were monitored by a committee composed of representatives of the Requestors, using generally-accepted standards. If significant changes from historical measures indicated that a physician had altered his or her referral patterns in a manner beneficial to the Hospital as a result of the Arrangement, the physician at issue would have been terminated from participation in the Arrangement. No physicians were terminated.

- The Executive Summary identified projected cost savings, and the aggregate payment to the Anesthesiology Group, when made, will not exceed 50% of those amounts.

The Hospital and the Anesthesiology Group documented the activities and the payment methodology under the Arrangement and agreed to make the documentation available to the Secretary of the United States Department of Health and Human Services, upon request. In addition, the Hospital and the Anesthesiology Group disclosed the Arrangement to patients, including the fact that the Anesthesiology Group's compensation was based on a percentage of the Hospital's cost savings. The disclosure was made to the patient before the patient was admitted to the Hospital for a procedure covered by the Arrangement; if pre-admission disclosure was impracticable (e.g., the patient was admitted for an unscheduled procedure or the need for the procedure was determined after admission), the disclosure was made before the patient consented to the surgery. The disclosures were in writing, and patients had an opportunity, if desired, to review details of the Arrangement, including the specific cost savings measures applicable to the patient's surgery.

II. LEGAL ANALYSIS

Arrangements like the Arrangement are designed to align incentives by offering physicians a portion of a hospital's cost savings in exchange for implementing cost saving strategies. Under the current reimbursement system, the burden of these costs falls on hospitals, not physicians. Payments to physicians based on cost savings may be intended to motivate them to reduce hospital costs associated with procedures performed at the hospital.

Properly structured, arrangements that share cost savings can serve legitimate business and medical purposes. Specifically, properly structured arrangements may increase efficiency and reduce waste, thereby potentially increasing a hospital's profitability. However, such arrangements can potentially influence physicians' judgment to the detriment of patient care. Our concerns include, but are not limited to, the following: (i) stinting on patient care; (ii) "cherry picking" healthy patients and steering sicker (and more costly) patients to hospitals that do not offer such arrangements; (iii) payments in exchange for patient

referrals; and (iv) unfair competition (a "race to the bottom") among hospitals offering cost savings programs to foster physician loyalty and to attract more referrals.

Hospital cost savings programs in general, and the Arrangement in particular, may implicate at least three Federal legal authorities: (i) the civil monetary penalty for reductions or limitations of direct patient care services provided to Federal health care program beneficiaries, sections 1128A(b)(1)-(2) of the Act; (ii) the anti-kickback statute, section 1128B(b) of the Act; and (iii) the physician self-referral law, section 1877 of the Act.[10] We address the first two of these authorities; section 1877 of the Act falls outside the scope of the OIG's advisory opinion authority. We express no opinion on the application of section 1877 of the Act to the Arrangement.

A. The Civil Monetary Penalty, Sections 1128A(b)(1)-(2) of the Act

Sections 1128A(b)(1)-(2) of the Act establish a civil monetary penalty ("CMP") against any hospital or critical access hospital that knowingly makes a payment directly or indirectly to a physician (and any physician that receives such a payment) as an inducement to reduce or limit items or services to Medicare or Medicaid beneficiaries under the physician's direct care. Hospitals that make (and physicians that receive) such payments are liable for CMPs of up to $2,000 per patient covered by the payments. See id. There is no requirement that the prohibited payment be tied to a specific patient or to a reduction in medically necessary care. The CMP applies only to reductions or limitations of items or services provided to Medicare and Medicaid fee-for-service beneficiaries.[11]

The CMP prohibits payments by hospitals to physicians that may induce physicians to reduce or limit items or services furnished to their Medicare and Medicaid patients. A

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[10]In addition, nonprofit hospital arrangements raise issues of private inurement and private benefit under the Internal Revenue Service's income tax regulations in connection with section 501(c)(3) of the Internal Revenue Code. See Rev. Rul. 69-383, 1969-2 C.B. 113. We express no opinion on the application of the Internal Revenue Code to the Arrangement.

[11]Physician incentive arrangements related to Medicare risk-based managed care contracts, similar Medicaid contracts, and Medicare Advantage plans (formerly Medicare + Choice) are subject to regulation by the Secretary pursuant to sections 1876(i)(8), 1903(m)(2)(A)(x), and 1852(j)(4) of the Act (respectively), in lieu of being subject to sections 1128A(b)(1)-(2). See OIG letter regarding hospital-physician incentive plans for Medicare and Medicaid beneficiaries enrolled in managed care plans (dated August 19, 1999), available at http://oig.hhs.gov/fraud/docs/alertsandbulletins/gsletter.htm. See also 42 C.F.R. § 417.479 (Medicare HMOs or competitive medical plans); 42 C.F.R. § 422.208 (Medicare Advantage plans); 42 C.F.R. § 438.6 (Medicaid risk plans).

threshold inquiry is whether the Arrangement might have induced the anesthesiologists in the Anesthesiology Group to reduce or limit items or services. Given the specificity of the Arrangement, it is possible to review the opportunities for savings individually and evaluate their potential impact on patient care.

Having reviewed the five individual recommendations, we conclude that the recommendations implicated the CMP. Simply put, the Arrangement might have induced physicians to reduce or limit the then-current medical practice at the Hospital. We recognize that the then-current medical practice may have involved care that exceeded the requirements of medical necessity. However, whether current medical practice reflects necessity or prudence is irrelevant for purposes of the CMP.

Notwithstanding, the Arrangement has several features that, in combination, provide sufficient safeguards so that we would not seek sanctions against the Requestors under sections 1128A(b)(1)-(2) of the Act.

First, the specific cost-saving actions and resulting savings were clearly and separately identified. The transparency of the Arrangement allowed, and will continue to allow, for public scrutiny and individual physician accountability for any adverse effects of the Arrangement, including any difference in treatment among patients based on nonclinical indicators. The transparency of the incentives for specific actions and specific procedures also facilitates accountability through the medical-legal professional liability system.

Second, the Requestors have proffered credible medical support for the position that implementation of the recommendations did not adversely affect patient care. The Arrangement was periodically reviewed by the Requestors to confirm that the Arrangement was not having an adverse impact on clinical care.[12]

Third, the amount to be paid under the Arrangement has been calcuated based on all surgeries regardless of the patients' insurance coverage, subject to the cap on payment for Federal health care program procedures. Moreover, the surgical procedures to which the Arrangement applied were not disproportionately performed on Federal health care program

[12]We have had the Arrangement reviewed by an independent medical expert. The medical expert concluded that the cost savings measures, as described in the advisory opinion request and supplemental submissions, should not adversely affect patient care. For purposes of this opinion, however, we rely solely on the Requestors' certifications and nothing in this advisory opinion should be construed as an endorsement or conclusion as to the medical propriety of the specific activities undertaken as part of the Arrangement.

beneficiaries. Additionally, the cost savings have been calculated on the Hospital's actual out-of-pocket acquisition costs, not an accounting convention.

Fourth, the Arrangement protected against inappropriate reductions in services by utilizing objective historical and clinical measures to establish baseline thresholds beyond which no savings accrued to the Anesthesiology Group. The Requestors have certified that the baseline measure establishing a "floor" for reduced use of the particular catheter was reasonably related to the Hospital's or comparable hospitals' practices and patient populations, and that the STS quality indicators against which all of the Arrangement's recommendations were evaluated reflect objective hospital baselines and incorporate specificity sufficient to correlate outcomes with operating room practices; the indicators are action-specific and not simply based on isolated patient outcome data unrelated to specific changes in operating room practices. No cost sharing amounts were allocated to the Anesthesiology Group where there were reductions in historical STS quality indicators.

Fifth, the product standardization recommendation protected against inappropriate reductions in services by ensuring that individual anesthesiologists still had available the same selection of fluid warming hot lines after implementation of the Arrangement as before. The Arrangement was designed to produce savings through inherent clinical and fiscal value and not from restricting the availability of devices.

Sixth, the Hospital and the Anesthesiology Group provided written disclosures of their involvement in the Arrangement to patients whose care may have been affected by the Arrangement and provided patients an opportunity to review the cost savings recommendations prior to admission to the Hospital (or, where pre-admission consent was impracticable, prior to consenting to surgery). While we do not believe that, standing alone, such disclosures offer sufficient protection from program or patient abuse, effective and meaningful disclosure offers some protection against possible abuses of patient trust.[13]

Seventh, the financial incentives under the Arrangement were reasonably limited in duration and amount.

Eighth, because the Anesthesiology Group distributes profits to its members on a per capita basis, any incentive for an individual anesthesiologist to generate disproportionate cost savings is mitigated.

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[13]Ordinarily, we would expect patient disclosures to be coupled with patient satisfaction surveys that closely monitor patient perceptions of their care. However, in the context of the Arrangement, which focuses on items used in operating rooms, we believe that patient satisfaction surveys would not be effective.

Our decision not to impose sanctions on the Requestors in connection with the Arrangement is an exercise of our discretion and is consistent with our Special Advisory Bulletin on "Gainsharing Arrangements and CMPs for Hospital Payments to Physicians to Reduce or Limit Services to Beneficiaries" (July 1999) (the "Special Advisory Bulletin"). We reiterate that the CMP applies to any payment by a hospital to a physician that is intended to induce the reduction or limitation of items or services to Medicare or Medicaid patients under the physician's direct clinical care. The Arrangement is markedly different from "gainsharing" plans that purport to pay physicians a percentage of generalized cost savings not tied to specific, identifiable cost-lowering activities. Importantly, the Arrangement set out the specific actions to be taken and tied the remuneration to the actual, verifiable cost savings attributable to those actions. This transparency allowed an assessment of the likely effect of the Arrangement on quality of care and ensured that the identified actions caused the savings.

"Gainsharing" plans can present substantial risks for both patient and program abuse – risks that are not present in the Arrangement. Given the limited duration and scope of the Arrangement, the safeguards provide sufficient protections against patient and program abuse. Other arrangements, including those that are more expansive in scope or less specific than the Arrangement, are likely to require additional or different safeguards.

B. The Anti-Kickback Statute

The anti-kickback statute makes it a criminal offense knowingly and willfully to offer, pay, solicit, or receive any remuneration to induce or reward referrals of items or services reimbursable by a Federal health care program. See section 1128B(b) of the Act. Where remuneration is paid purposefully to induce or reward referrals of items or services payable by a Federal health care program, the anti-kickback statute is violated. By its terms, the statute ascribes criminal liability to parties on both sides of an impermissible "kickback" transaction. For purposes of the anti-kickback statute, "remuneration" includes the transfer of anything of value, directly or indirectly, overtly or covertly, in cash or in kind.

The statute has been interpreted to cover any arrangement where one purpose of the remuneration was to obtain money for the referral of services or to induce further referrals. United States v. Kats, 871 F.2d 105 (9th Cir. 1989); United States v. Greber, 760 F.2d 68 (3d Cir.), cert. denied, 474 U.S. 988 (1985). Violation of the statute constitutes a felony punishable by a maximum fine of $25,000, imprisonment up to five years, or both. Conviction will also lead to automatic exclusion from Federal health care programs, including Medicare and Medicaid. Where a party commits an act described in section 1128B(b) of the Act, the OIG may initiate administrative proceedings to impose civil monetary penalties on such party under section 1128A(a)(7) of the Act. The OIG may also

initiate administrative proceedings to exclude such party from the Federal health care programs under section 1128(b)(7) of the Act.

The Department of Health and Human Services has promulgated safe harbor regulations that define practices that are not subject to the anti-kickback statute because such practices would be unlikely to result in fraud or abuse. See 42 C.F.R. § 1001.952. The safe harbors set forth specific conditions that, if met, assure entities involved of not being prosecuted or sanctioned for the arrangement qualifying for the safe harbor. However, safe harbor protection is afforded only to those arrangements that precisely meet all of the conditions set forth in the safe harbor.

The safe harbor for personal services and management contracts, 42 C.F.R. §1001.952(d), is potentially applicable to the Arrangement. In relevant part for purposes of this advisory opinion, the personal services safe harbor requires that the aggregate compensation paid for the services be set in advance and consistent with fair market value in arm's-length transactions. The Arrangement can not fit in the safe harbor because the payment owed to the Anesthesiology Group was calculated on a percentage basis, and thus the aggregate compensation was not set in advance. However, the absence of safe harbor protection is not fatal. Instead, the Arrangement must be subject to case-by-case evaluation.

As with any compensation arrangement between a hospital and a physician potentially in a position to generate business, directly or indirectly, for the hospital, we are concerned that the Arrangement could have been used to disguise remuneration from the Hospital to the Anesthesiology Group or its anesthesiologists. Under the Arrangement, the anesthesiologists would receive not only their professional fees, but also, indirectly, a share of the Hospital's payment, depending on cost savings. In other words, the more anesthesia services an anesthesiologist furnishes at the Hospital, the more money he or she is likely to receive under the Arrangement. Thus, the Arrangement will generate remuneration for the anesthesiologists.

Typically, anesthesiologists are less likely to generate business for hospitals than many other types of physicians, although some anesthesiologists perform procedures themselves (e.g., pain management procedures), order additional items or services for existing patients, or otherwise generate Federally payable business for hospitals. Thus, depending on the facts, anesthesiologists may be in a position, directly or indirectly, to generate Federal health care program business, and purposeful payments to induce such business would run afoul of the statute. Here, it appears unlikely that the anesthesiologists in the Anesthesiology Group are in a position to generate Federal health care program business for the Hospital. The nature of the specific services furnished by the Anesthesiology Group at the Hospital, as well as the nature of the relationship between the parties (including the fact that the anesthesiologists do not reassign their right to payment to the Hospital),

substantially limit the opportunities for the Anesthesiology Group to generate Federal health care program business for the Hospital.[14]

The structure of the Arrangement adequately addresses any residual risk of improper referral payments.

First, participation in the Arrangement was limited to anesthesiologists already on the medical staff, thus limiting the likelihood that the Arrangement would have attracted other anesthesiologists to the Hospital. In addition, the potential savings derived from procedures for Federal health care program beneficiaries were capped based on the prior year's admissions of Federal health care program beneficiaries. Finally, the contract year for which payments were calculated was limited to one year, reducing any incentive for anesthesiologists to switch facilities to earn cost sharing payments, and patient admissions were monitored for changes in severity, age, or payor to ensure that the Arrangement did not result in inappropriate changes in referral patterns. Thus, while the incentive to generate business was not necessarily eliminated, it was substantially reduced.

Second, the structure of the Arrangement eliminated the risk that the Arrangement was used to reward physicians who referred patients to, or otherwise generated business for, the Hospital, the Anesthesiology Group, or its anesthesiologists. The Anesthesiology Group is the sole participant in the Arrangement and is composed entirely of anesthesiologists; no cardiologists, cardiac surgeons, or other physicians are members of the Anesthesiology Group or share in its profit distributions. Within the Anesthesiology Group, profits are distributed to its members on a per capita basis, mitigating any incentive for an individual anesthesiologist to generate disproportionate cost savings.

Third, the Arrangement set out with specificity the particular actions that generated the cost savings on which the payments were based. The recommendations in the Executive Summary represented a change in operating room practice, for which the anesthesiologist was responsible and had liability exposure. It is not unreasonable for the anesthesiologist to receive compensation for the increased risk from the changes in practice. Moreover, the payments to be made represent a portion of one year's worth of cost savings and are limited in amount (i.e., the aggregate cap), duration (i.e., the limited term), and scope (i.e., the total savings that can be achieved from the implementation of any one recommendation were limited by appropriate utilization levels). The payments under the Arrangement do not appear unreasonable, given, among other things, the nature of the actions required of the

[14]Moreover, we note that the typical anti-kickback concern about arrangements between hospitals and anesthesiologists is the risk of remuneration flowing from the anesthesiologists to the hospital in return for hospital business.

anesthesiologists to implement the five recommended actions, the specificity of the payment formula, and the cap on total remuneration to the Anesthesiology Group.[15] We caution that payments of 50% of cost savings in other arrangements, including multi-year arrangements or arrangements with generalized cost savings formulae, could well lead to a different result.

In light of these circumstances and safeguards, the Arrangement poses a low risk of fraud or abuse under the anti-kickback statute.

III. CONCLUSION

Notwithstanding the foregoing, we reiterate our concerns regarding many arrangements between hospitals and physicians to share cost savings. Improperly designed or implemented arrangements risk adversely affecting patient care and could be vehicles to disguise payments for referrals. For example, an arrangement that cannot be adequately and accurately measured for quality of care would pose a high risk of fraud or abuse, as would one that rewards physicians based on overall cost savings without accountability for specific cost reduction measures. Moreover, arrangements structured so as to pose a heightened potential for patient steering and unfair competition would be considered suspect. In short, this opinion is predicated on the specific arrangement posed by the Requestors and is limited to that specific arrangement. Other apparently similar arrangements could raise different concerns and lead to a different result.

Based on the facts certified in your request for an advisory opinion and supplemental submissions, we conclude: (i) the Arrangement could constitute an improper payment to induce reduction or limitation of services pursuant to sections 1128A(b)(1)-(2) of the Act, but that the OIG would not impose sanctions under sections 1128A(b)(1)-(2) on the Requestors in connection with the Arrangement; and (ii) the Arrangement could potentially generate prohibited remuneration under the anti-kickback statute, if the requisite intent to induce or reward referrals of Federal health care program business were present, but that the OIG would not impose administrative sanctions on the Requestors under sections 1128(b)(7) or 1128A(a)(7) of the Act (as those sections relate to the commission of acts described in section 1128B(b) of the Act) in connection with the Arrangement.

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[15]We are precluded by statute from opining on whether fair market value shall be or was paid for goods, services, or property. See 42 U.S.C. § 1320a-7d(b)(3)(A). While the Requestors have certified that the payments under the Arrangement are consistent with fair market value, we do not rely on that certification in this opinion, nor have we made an independent fair market value assessment.

IV. LIMITATIONS

The limitations applicable to this opinion include the following:

- This advisory opinion is issued only to [names redacted], the requestors of this opinion. This advisory opinion has no application to, and cannot be relied upon by, any other individual or entity.

- This advisory opinion may not be introduced into evidence in any matter involving an entity or individual that is not a requestor to this opinion.

- This advisory opinion is applicable only to the statutory provisions specifically noted above. No opinion is expressed or implied herein with respect to the application of any other Federal, state, or local statute, rule, regulation, ordinance, or other law that may be applicable to the Arrangement, including, without limitation, the physician self-referral law, section 1877 of the Act.

- This advisory opinion will not bind or obligate any agency other than the U.S. Department of Health and Human Services.

- This advisory opinion is limited in scope to the specific arrangement described in this letter and has no applicability to other arrangements, even those that appear similar in nature or scope.

- No opinion is expressed herein regarding the liability of any party under the False Claims Act or other legal authorities for any improper billing, claims submission, cost reporting, or related conduct.

This opinion is also subject to any additional limitations set forth at 42 C.F.R. Part 1008.

The OIG will not proceed against the Requestors with respect to any action that is part of the Arrangement taken in good faith reliance upon this advisory opinion, as long as all of the material facts have been fully, completely, and accurately presented, and the Arrangement in practice comports with the information provided. The OIG reserves the right to reconsider the questions and issues raised in this advisory opinion and, where the public interest requires, to rescind, modify, or terminate this opinion. In the event that this advisory opinion is modified or terminated, the OIG will not proceed against the Requestors with respect to any action taken in good faith reliance upon this advisory opinion, where all of the relevant facts were fully, completely, and accurately presented, and where such action was promptly discontinued upon notification of the modification or termination of this

advisory opinion. An advisory opinion may be rescinded only if the relevant and material facts have not been fully, completely, and accurately disclosed to the OIG.

Sincerely,

/s/

Lewis Morris
Chief Counsel to the Inspector General

[Appendix A redacted]